chemwerth INC

85 RIMMON ROAD WOODBRIDGE CT 06525 USA
203 397 8132 *fax*
www.chemwerth.com

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June 4, 1999

Philip Chao
Office of Policy (HF-23)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD. 20857

Dear Philip:

ChemWerth Inc. is a representative/agent for several foreign establishment manufacturers of bulk drug substances. Our position is in full support of the spirit of the proposed rule. We would like to comment on the Proposed Rules §207.40(c) published in the Federal Register May 14, 1999 Vol. 64, No. 93. Our position is that foreign establishments should assign one agent for each specific product to be sold in the United States.

The statement "to require each foreign establishment to submit the name, address and phone number of its United States agent as part of the establishment's initial and updated registration information. As stated earlier the FDA interprets section 510(i) of the act as allowing for only one United States agent for each foreign establishment."

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PINE CITY PLAZA SUITE 808, 8 DONG AN ROAD
SHANGHAI 200032 CHINA
86 21 64435636 (37,38,39)
86 21 64431547 *fax*
cwchina@prodigychina.com

C4

chemwerth INC

85 RIMMON ROAD WOODBRIDGE CT 06525 USA
203 387 7794
203 397 8132 *fax*
www.chemwerth.com

Comment:

Many foreign firms manufacture multiple bulk drug substances. A specific firm may manufacture both Veterinary grade products and injectable grade oncology drugs. To force a foreign firm to select one agent for the entire product line is not practical. The expertise of each agent in a specific field would be lost and cause potential harm. We recommend that each foreign firm chose a single agent for each identified product that is intended to be sold in the United States. This agent would also be identified in the Drug Master File application or Veterinary Master File application. This information could also be listed on the Drug Master File data base and avoid confusion.

Example:

Our firm represents a foreign firm for (4) oncology bulk drug substances and (1) veterinary drug. The facility is also selling (3) oral drug products through another agent. Our customers and expertise with the FDA lies with the products we represent. Another firm works on the oral products. The act would force the foreign firm to choose a single agent and seriously effect their relationships with their customers and the FDA. One agent per product in this instance is practical.

Sincerely,

Peter Werth III
ChemWerth Inc.

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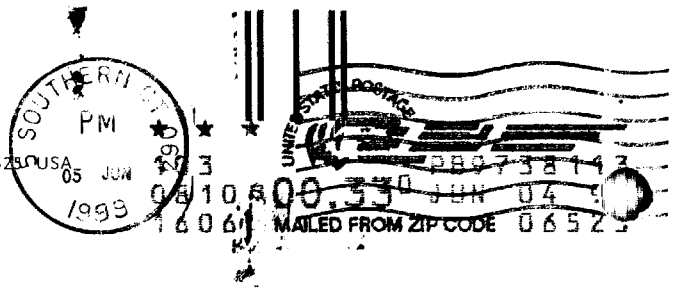

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